

REMARKS

The Applicant respectfully requests reconsideration of the present application in view of the following remarks of the attached Declaration Under 37 C.F.R. § 1.131, which accompanies this response, which are responsive to the Non-Final Office Action mailed April 27, 2010.

I. Status of Claims

In the Office Action, Claims 1-11, 13-26 and 28-90 were noted as pending in the application and were rejected. Claims 31-90, previously withdrawn, have been cancelled herein without prejudice. As a result of this response, Claims 1-11, 13-26 and 28-30 remain pending, and Claims 1 and 16 have been amended in order to further clarify the claimed invention.

II. Claim Rejections

a. 35 U.S.C. § 103(a)

In the Office Action, claims 1-11, 13-26, and 28-30 are rejected under 35 U.S.C. §103(a) as being unpatentable over, “Combined Ultrasound and Fluorescence Spectroscopy for Physico-Chemical Imaging of Atherosclerosis,” IEEE Transactions on Biomedical Engineering 42(2) (1995): 121-132, by Warren, *et al.* (“Warren”) in view of Tomography – Definition from Dictionary.com and Peter et al (“Peter”), “Design Study of a Novel Dual-Modality Emission Micro-Imaging Tomography for Radiopharmaceutical and Bioluminescent/Fluorescent Molecular Approaches,” IEEE Int’l Symp. On Biomedical Imaging Proceedings (2002): 797-900. (Office Action, pg. 3).

For at least the following reasons, Applicant respectfully requests that the rejection of Claims 1-11, 13-26, and 28-30 under 35 U.S.C. § 103(a) be withdrawn.

i. Applicant Conceived and Diligently Reduced to Practice the Claimed Invention Prior to *Peter*

Applicant submits herewith a Declaration Under 37 C.F.R. § 1.131 indicating that prior to July 7, 2002, the date that *Peter* was presented at the 2002 IEEE International Symposium on

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Biomedical Imaging (July 7-10, 2002, Washington, D.C.), the inventors of the present application had conceived and diligently pursued reducing to practice the invention claimed in the present application in the United States or a NAFTA or WTO member country. As such, Applicant respectfully submits that *Warren* in view of Tomography – Definition from Dictionary.com and *Peter* cannot be used to reject Claims 1-11, 13-26, and 28-30 under 35 U.S.C. § 103(a).

As *Warren* in view of Tomography – Definition from Dictionary.com fails to teach, suggest or make obvious all of the limitations of the claimed invention, Applicant submits that Claims 1-11, 13-26, and 28-30 are in a form for allowance.

**ii. *Warren* in view of Tomography – Definition from Dictionary.com and
Peter Fails to Create a Prima Facie Case of Obviousness**

Assuming, arguendo, that *Peter* was considered to be appropriate prior art to the invention disclosed in the present application, Applicant respectfully submits that *Warren* in view of Tomography – Definition from Dictionary.com and *Peter* fails to create a prima facie case of obviousness.

1. Independent Claims 1 and 16

The Examiner has the burden of establishing a prima facie case of obviousness under 35 U.S.C. § 103(a). *Ex Parte Martin P. Hageman and Thomas J. Palus*, Appeal No. 2000-1514, Application No. 09/038,450 (citing *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993)); *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 U.S.P.Q. 785, 788 (Fed. Cir. 1984). Only if the Examiner satisfies this initial burden does the burden of coming forward with evidence shift to the Appellant. *Id.* The Examiner can satisfy this burden by showing some objective teaching in the prior art or knowledge generally available to one of ordinary skill in the art suggests the claimed subject matter. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988).

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A *prima facie* case of obviousness requires: (1) a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings; (2) a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); *In re Fine*, 87 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); MPEP § 2142, 8th Ed., Rev. 4. Furthermore, rejections based on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be explicit analysis including some rational underpinning to support the legal conclusion of obviousness. *K.S.R. International Co. v. Teleflex, Inc.*, et al., 550 U.S. 14 (April 2007), citing *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006).

The Office Action provides that *Warren* "discloses a method and system for reconstructing a bioluminescent source distribution within an object[,"] citing line 1 of the abstract of *Warren* (Office Action, pg. 3, emphasis added). Applicant respectfully traverses that assertion. Line 1 of the abstract of *Warren* recites: "This paper describes a combined ultrasonic and spectroscopic system for remotely obtaining physico-chemical images of normal arterial tissue and atherosclerotic plaque." *Warren* fails to teach or suggest a method and system for reconstructing a bioluminescent source distribution within an object as *Warren* discloses only determining the chemical composition of a sample by "fitting its fluorescence spectrum (in calibrated units) to a model of tissue fluorescence incorporating protein and hemoglobin attenuation" and compensating for distance variation (*Warren*, Abstract). *Warren* teaches only fluorescence and does not teach bioluminescence.

As set forth in previous papers in this case, fluorescence is significantly different from bioluminescence at least in the requirement that fluorescence derives its excitation from an external source. The knowledge of one of skill in the art is clear that there is a difference between bioluminescence and fluorescence. To reconstruct a fluorescent image, the interference created by the external light source to excite the fluorescent source and the process of fluorescent

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light being directed toward the external detectors have to be taken into account. In contrast, bioluminescence imaging is not complicated by the fluorescence issues. Hence, bioluminescence imaging has a much better signal to noise ratio or sensitivity than fluorescent imaging. Light energy must be delivered at a potential source of fluorescence in order to cause emission of fluorescent light. This is not the case with bioluminescence. Bioluminescence does not make use of any external light source. Bioluminescence signals are self generated by the bioluminescent light source without stimulation from an external energy source. Applicant refers to prior responses on the differences between fluorescence and bioluminescence.

Therefore, Applicant submits that as *Warren* fails to teach, suggest or make obvious “a method and system for reconstructing a bioluminescent source distribution within an object,” then *Warren* cannot teach, suggest or make obvious “reconstructing a bioluminescent source distribution of the object from the internally derived bioluminescent signals based on the mapped optical properties, with a radiative transfer equation or an approximation to the radiative transfer equation[,]” as recited in Claims 1 and 16, as amended.

Furthermore, the Office Action states that *Warren* teaches producing “a bioluminescent source distribution (page 126, col. 1, lines 54-58; page 123 Monte Carlo radiative transfer model), based on the mapped optical properties (page 126, col. 1, lines 54-58).” (Office Action, pg. 3). Applicant respectfully traverses this assertion. Page 126, col. 1, lines 54-58 of *Warren* provides: “Finally, a combined fluorescence/ultrasound image of a section of aorta containing normal and atherosclerotic tissue was produced with the system by obtaining *fluorescence spectra* and ultrasound reflection times at a series of adjacent pixels along the intimal surface.” (Emphasis added.) As noted above, *fluorescence differs significantly from bioluminescence* and cannot be used interchangeably. Therefore, *Warren* fails to teach, suggest or make obvious “reconstructing a bioluminescent source distribution of the object from the internally derived bioluminescent signals based on the mapped optical properties, with a radiative transfer equation or an approximation to the radiative transfer equation[,]” as recited in Claims 1 and 16, as amended.

Tomography – Definition from Dictionary.com and *Peter* likewise fails to teach or suggest “reconstructing a bioluminescent source distribution of the object from the internally

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derived bioluminescent signals based on the mapped optical properties, with a radiative transfer equation or an approximation to the radiative transfer equation.” In fact, the Office Action cites *Peter* for different purposes. In particular, the Examiner cites *Peter* as teaching “a dual-modality imaging system comprising a tomographic imaging device and a bioluminescent/fluorescent imaging device ...” where “... the bioluminescent/fluorescent imaging device is capable of detecting both bioluminescent signals and fluorescent signals.” (Office Action, pg. 4). Furthermore, *Peter* admits that it does not teach or suggest reconstruction strategies; therefore, *Peter* cannot teach, suggest or make obvious teaches against “reconstructing a bioluminescent source distribution of the object from the internally derived bioluminescent signals based on the mapped optical properties, with a radiative transfer equation or an approximation to the radiative transfer equation.” *Peter* provides:

“Based on these initial investigations, we propose to design and assemble two concepts of a dual-modality (multi-)pinhole aperture micro-tomograph and also propose to develop and implement **reconstruction strategies (not included in this study)** that take into account multi-energetic count rate distributions and that statistically optimal account for the effects of scatter, attenuation, and geometric response of the tomograph and for spillover, partial volume, and related effects (if any) of the dual-modality approach.” (*Peter*, col. 1, pg. 798, emphasis added.)

Peter plainly states that the study described in the publication does not include reconstruction. Since both of the cited references fail to teach or suggest “reconstructing a bioluminescent source distribution of the object from the internally derived bioluminescent signals based on the mapped optical properties, with a radiative transfer equation or an approximation to the radiative transfer equation[,]” the cited references, even if combined, do not teach or suggest all of the recitations of independent Claims 1 or 16.

For at least the reasons discussed above, Applicant respectfully submits that independent Claims 1 and 16 are patentable over *Warren* in view of Tomography – Definition from Dictionary.com and *Peter*. Applicant, therefore, respectfully requests that the rejection of independent Claims 1 and 16 be withdrawn.

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2. Dependent Claims 2-11, 13-15, 17-26, and 28-30

Claims 2-11, 13-15, 17-26, and 28-30 depend, respectively, from independent Claims 1 and 16, and include all of the recitations of their base claims and any intervening claims plus their additional recitations that further distinguish the art applied in the rejection. Thus, for at least the reasons set forth above with respect to independent Claims 1 and 16, it is respectfully submitted that dependent Claims 2-11, 13-15, 17-26, and 28-30 are further patentable over *Warren* in view of Tomography – Definition from Dictionary.com and *Peter* as such dependent claims now depend from allowable base claims.

III. Conclusion

In light of the remarks above, Applicant respectfully submits that the application is in condition for allowance and respectfully requests that a Notice of Allowance be issued. The Examiner is encouraged to contact Applicant's undersigned attorney to resolve any remaining issues in order to expedite examination of the present application.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 14-0629.

Respectfully submitted,

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